

**REMARKS**

Claims 1, 3-17 and 19-32 are pending. Claims 2 and 18 have been canceled. Claims 1, 3-15 and 17 have been withdrawn from consideration.

Claim 1 has been amended for clarity.

New claim 32 finds support at page 13, line 19.

No new matter has been added by way of the above amendments.

**I. Issues Under 35 U.S.C. §103(a)**

The following prior art based Rejections are pending:

- (A) Claims 16, 19, 21-23, 25,26, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takenishi et al. (EP 555,980) in view of Mychajlowskij et al. (US Pat. 5,945,245);
- (B) Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takenishi et al. (EP 555,980) in view of Mychajlowskij et al. (US Pat. 5,945,245) as applied to claim 16 above, and further in view of Babler (US Pat. 6,800,127);
- (C) Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takenishi et al. (EP 555,980) in view of Mychajlowskij et al. (US Pat. 5,945,245) as applied to claim 16 above, and further in view of Nambu et al. (US Pat. 5,596,056); and
- (D) Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takenishi et al. (EP 555,980) in view of Mychajlowskij et al. as applied to claim 26 above, and further in view of Tomita et al. (US 2001/0026898).

Applicants respectfully traverse Rejections A-D.

The present invention is drawn to a process comprising

*a first step* of forming a compositional structure by **melt-kneading** an organic solid polymer component (A), a coloring agent (B) and a water-soluble auxiliary component (C) comprising at least an oligosaccharide (C1),

wherein this melt-kneading step forms the compositional structure having:

i) a matrix (continuous phase) comprising the water-soluble auxiliary component (C), and

ii) a particulate dispersed phase comprising the organic solid polymer component (A) and the coloring agent (B), and being dispersed in the matrix (continuous phase),

wherein the process further comprises *a second step* of eluting the water soluble auxiliary component (C) from the composition to produce a particle comprising the organic solid component (A) and the coloring agent (B).

In other words, the final product is in the form of particles comprising (A) and (B) in view of the step of eluting the matrix (continuous phase) of (C) from the compositional structure.

Clearly, the presently claimed process has significant patentable distinctions from the teachings of Takenishi et al. Takenishi et al. merely teach the formation of spherical particle of a water soluble polymer by **spray drying**. This can be naturally understandable from the fact that Takenishi et al. utilize an aqueous solution containing a water soluble polymer and an oligosaccharide in relation to the spray drying step. Since a solution such as the aqueous solution is necessary for spray drying, the artisan would not find any suggestion in Takenishi et al to perform a melt-kneading step. Moreover, since Takenishi et al. form polymer particles by spray drying with use of an aqueous solution, the kind of polymers are strictly limited. Additionally, a crosslinking step is necessary as a subsequent step for obtaining water-insoluble polymer particles.

Accordingly, significant patentable distinctions exist between the teachings of Takenishi et al and the present invention. In order to cure these deficiencies, the Examiner cites the secondary references to Mychajlowskij et al., Babler, Nambu et al. and Tomita et al. to cure the deficiencies of Takenishi et al. Applicants note that none of these secondary references teach or suggest a melt-kneading step or a step of eluting an oligosaccharide. Thus, even if the secondary references are combined with Takenishi et al., the present invention would never be constructed and advantages of the present invention would never be predicted from the cited references.

Accordingly, the present invention defines patentable subject matter and withdrawal of Rejections A-D is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

#### Conclusion

In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., Esq., Reg. No. 43,575 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.


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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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